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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,851	03/21/2002	Philippe Msika	REGIM 3.3-012	2236
530 7590 02/17/2010 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090				
EXAMINER FLOOD, MICHELE C				
ART UNIT		PAPER NUMBER		
1655				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/088,851

Applicant(s)

MSIKA ET AL.

Examiner

MICHELE FLOOD

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61, 62, 70-72, 76, 77, 82, 84, 85 and 88-92 is/are pending in the application.
- 4a) Of the above claim(s) 88-90 and 92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61, 62, 70-72, 76, 77, 82, 84, 85 and 91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-544)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on September 20, 2009.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection or objection present in the previous Office action mail dated April 1, 2009 and not repeated herein is withdrawn.

Claims 61, 62, 70-72, 76, 77, 82, 84, 85 and 91 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 112

Claims 61, 62, 70-72, 76, 77, 82, 84, 85 and 91, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

The metes and bounds of each of Claims 61 and 91, as drafted in its entirety, are rendered vague and indefinite but particularly by the limitation :wherein said condition is sensitive skin, dry skin, pruritus, ichthyosis, acne, xerosis, atopic dermatitis, cutaneous desquamation, skin subjected to actinic radiation, or skin subjected to ultraviolet (UV) radiation" because this limitation in addition to reciting skin conditions set forth in the language of the preamble also recites skin conditions other than those recited in the preamble. Therefore, it is uncertain as to the subject matter to which

Applicant seeks patent protection. Is the claimed invention directed to a method of treating any of atopic dermatitis, sensitive skin, irritated skin or sensitive skin? Or, is the claimed invention directed to a method of treating any of the skin conditions recited in the claim-designated Markush group of either claim. The lack of clarity renders the claims vague and indefinite.

All other cited claims depend directly or indirectly from rejected claims and are, and; therefore, are also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

Claims 61, 62, 70-72, 76, 77, 82, 84, 85 and 91, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Loden et al. (Loden, M. et al. The British Journal of Dermatology (2/1996), 134(2): 215-220. Effect of topically applied lipids on surfactant-irritated skin.) and Sekimoto (JP 57131716 A) in view of Milkova et al. (Milkova T et al. Nahrung (1977); 21(1): 1-6. Study on the chemical nature of sterols contained in Bulgarian sunflower oil.), Alonso et al. (Alonso L et al. Journal of the American Oil Chemists' Society (1997); 74(2): 131-135. Determination of mixtures in vegetable oils and milk by fat analysis of sterol fraction by gas chromatography.) and Brun et al. (GB 2066071 A). Newly applied as necessitated by amendment.

Applicant claims a method of treating a skin condition selected from the group selected from atopic dermatitis, sensitive skin, irritated skin, and reactive skin of a subject having a quantity of skin lipids comprising administering an effective amount of

a composition comprising at least one plant oil product selected from the group consisting of oil distillate of sunflower oil and unsaponifiable materials from sunflower oil; wherein said quantity of skin lipids increases after administration of the composition, wherein said skin lipids that increase after administration are selected from the group consisting of cholesterol, ceramide 1, and ceramide 2; and wherein the skin condition is sensitive skin, dry skin, pruritus, ichthyosis, acne, xerosis, atopic dermatitis, cutaneous desquamation, skin subjected to actinic radiation or skin subjected to ultraviolet (UV) radiation. Applicant further claims the method of claim 61 wherein the subject has an epidermal skin barrier and the skin lipids are lipids of the epidermal skin barrier; wherein the plant oil product is present in an amount of between about 0.01% and 100% by weight relative to the total weight of the composition; wherein the composition is administered topically, orally, enterally or parenterally; wherein the composition is applied to the skin, the neighboring mucous membranes and/or the integuments; and, wherein the composition is administered to treat skin that is sensitive, irritated or reactive. Applicant further claims the method of claim 71, wherein said unsaponifiable materials are present in said plant oil product in an amount of 10 to 20% by weight. Applicant further claims the method of claim 84, wherein the composition is a cosmetic, pharmaceutical or dermatological composition; wherein the cosmetic, pharmaceutical or dermatological composition comprises an oil solution, a water-in-oil emulsion, an oil-in-water emulsion, a micro-emulsion, an oily gel, an anhydrous gel or a dispersion of vesicles, microcapsules or microparticles.

Applicant claims a method of treating a skin condition selected from the group selected from atopic dermatitis, sensitive skin, irritated skin, and reactive skin of a subject having a quantity of skin lipids comprising administering an effective amount of a composition comprising at least one plant oil product selected from the group consisting of oil distillate of sunflower oil and unsaponifiable materials from sunflower oil; wherein said quantity of skin lipids increases after administration of said composition, wherein said skin lipids that increases after administration are selected from the group consisting of cholesterol, and ceramides; and wherein the skin condition is sensitive skin, dry skin, pruritus, ichthyosis, acne, xerosis, atopic dermatitis, cutaneous desquamation, skin subjected to actinic radiation or skin subjected to ultraviolet (UV) radiation.

Loden teaches a method of treating irritated skin or sensitive skin or dry skin comprising topically administering an effective amount of canola oil and its fraction of unsaponifiable material (mainly beta-sitosterol; and, campesterol and brassicasterol and fatty acids) to treat skin treated with sodium lauryl sulfate (SLS). Loden teaches that canola oil and its sterol-enriched fraction had beneficial oil effects on reducing skin irritation, erythema and decreasing transepidermal water loss. While Loden suggests the possibility that sterol-enriched canola oil assists the skin in supplying the SLS-damaged skin barrier with adequate lipids, Loden does not specifically teach that skin lipids of either cholesterol or ceramide (ceramide 1 or ceramide 2) increase after administration of the oil.

Sekimoto teaches a method of administering an effective amount of a composition comprising sitosterol obtained from various vegetable oils (e.g. soybean oil, etc.), for the treatment of dry skin and keratinization and softening of skin. The composition taught by Sekimoto comprises 0.3% sitosterol or 2.0% of sitosterol-containing vegetable oils. Sekimoto further teaches that the method of administering the referenced composition increases the level of skin lipids in treated patients. Sekimoto further teaches that administration of unsaponifiable materials from the oils. Sekimoto further teaches, "GLC analysis of the fluid secreted from the sole of a foot showed that it contained cholesterol, sitosterol and triterpene alcohols. The content of sitosterol in the secreted fluid is higher than that in blood. Sitosterol was found to exhibit an effect against drying of the surface of foot-sole and keratinisation of the skin". Thus, it was known in the art at the time of the invention that sterol-enriched vegetable oils are useful in increasing the quantity of cholesterol in the skin of a subject. Therefore, an artisan of ordinary skill would have had a reasonable expectation that topical administration of sterol-enriched canola oil to increase skin lipids would be successful. This reasonable expectation of success would have motivated the artisan to use the canola oil product of Loden to increase skin lipids in a subject having sensitive skin, irritated skin and/or reactive skin, particularly in view of the beneficial functional effects that it was shown to reduce skin irritation, reduce transepidermal water loss absent skin sensitization; and the suggestion of Loden that that sterol-enriched canola oil assists the skin in supplying SLS-damaged skin barrier with adequate lipids.

The combined teachings of Loden and Sekimoto, as set forth above, teach the instantly claimed invention except for administering an effective amount of a composition comprising at least one plant oil product selected from the group consisting of oil distillate of sunflower oil and unsaponifiable materials from sunflower oil. However, it would have been obvious to one of ordinary skill in the art to add either of the instantly claimed ingredients to the method composition taught by the combined references or to replace the method composition taught by the combined references with either of the claim-designated ingredients to provide the claimed method of treating a skin condition because at the time the invention was made Milkova taught that the major sterols of sterol fractions of crude sunflower oil, as well as those of the technical lecithin, the pitch and the deodorizer distillate of the latter oil, are sitosterol, campesterol and stigmasterol; Alonso also taught that unsaponifiable materials from sunflower oil comprise sitosterol, campesterol and stigmasterol; and, moreover, Brun taught a composition comprising a mixture of avocado oil and/or jojoba oil and sunflower oil and at least one unsaponifiable of jojoba oil and/or at least one unsaponifiable or avocado oil, by weight from 20-45%, and/or at least one unsaponifiable of sunflower oil, by weight from 25-40%, that was useful in the making of cosmetics having lubricating properties and leaving a hydrophobic film on the surface of the skin to improve or maintain the suppleness of skin by preventing water evaporation from the skin. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add either of the claim-designated ingredients to the method composition taught by the combined references or

to replace the method composition taught by the combined references with either of the claim-designated ingredients to provide the claimed method of treating any of the claim-designated skin conditions because like Alonso, Milkova taught that distillate of sunflower oil and unsaponifiable materials from sunflower oil comprise the same or essentially the same sterol fractions contained in the unsaponifiable sterol fraction of vegetable oils comprising sitosterol taught by the combined references having the beneficial functional effect of increasing skin lipids in persons having dry skin or keratinized skin conditions (Please note that the pathological sequelae of atopic dermatitis is characterized by dry skin an/or keratinized skin, as well as a decrease of cholesterol and/or ceramide skin lipids, particularly in the plantar skin of atopic dermatitis patients; see Di Nardo et al. (U**), for example.); and Brun, like Loden, suggested that compositions comprising unsaponifiable materials from sunflower oil were useful in methods of treating dry senile, dry or rough skin or skin conditions related to dysfunctional skin barriers with transepidermal water loss, on page 1, lines 71-75. Thus, given the references before him or her, the instantly claimed method of treatment would have been no more than a matter of routine optimization to provide a result effect variable for either the addition or replacement of one functional equivalent for the other wherein it would be highly reasonable to assume that compositions comprising the same or essentially the same ingredients would provide the same beneficial functional effect for treating skin that is dry, sensitive, irritated or reactive and increasing skin lipids.

As the teachings of the references indicate that the various proportions and amounts of the ingredients used in the claim-designated composition(s) for the claimed method of treating skin condition are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

**This reference is cited merely to relay an intrinsic property and is not used herein on the basis for rejection *per se*.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
January 2, 2010

/Michele Flood/
Primary Examiner, Art Unit 1655